

NEW DIETARY INGREDIENT NOTIFICATION FOR OMEGA-3 PHOSPHOLIPIDS

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In accordance with the Dietary Supplement Health and Education Act of 1994 (DSHEA), 21 U.S.C. §350b (a) (2), and with final regulations (21 CFR § 190.6) published in the Federal Register (FDA, 1997a) "Requirement for Premarket Notification", the following information is submitted by Natural Inc. in support of a New Dietary Ingredient Notification for Omega-3 phospholipids (Omega-3 PL). Natural Inc. intends to market Omega-3 PL as a dietary supplement in the United States. The term "dietary supplement" is defined in 21 U.S.C. 321(ff) as, among other things, a "product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)." Omega-3 PL is a dietary ingredient that may be lawfully used in dietary supplements, in accordance with 21 U.S.C. 321 (ff)(1)(E). As per the statutes of the DSHEA, 21 U.S.C. § 350b (a) (2), Natural Inc. will not introduce, market, distribute or sell Omega-3 PL until at least 75 days following official acknowledgement of the receipt of this notification by the U.S. Food and Drug Administration (FDA).

SECTION 1

The name and complete address of the manufacturer of the dietary supplement that contains the dietary ingredient, or the dietary ingredient.

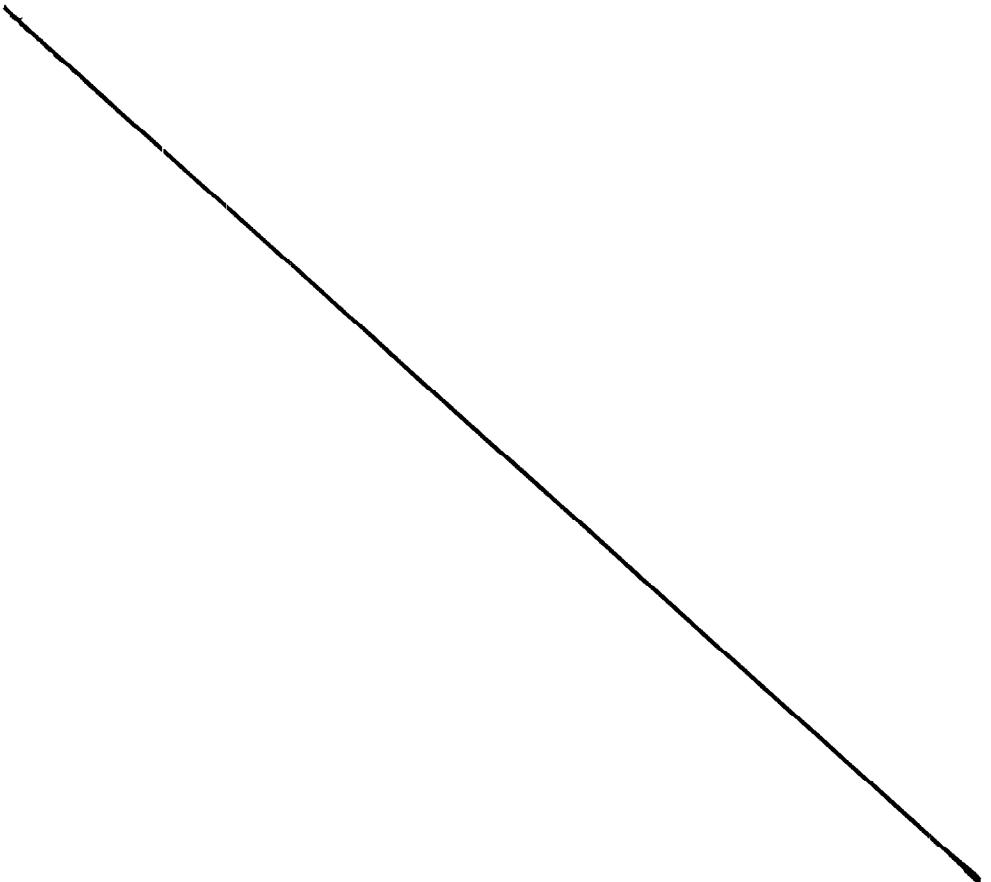
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SECTION 2

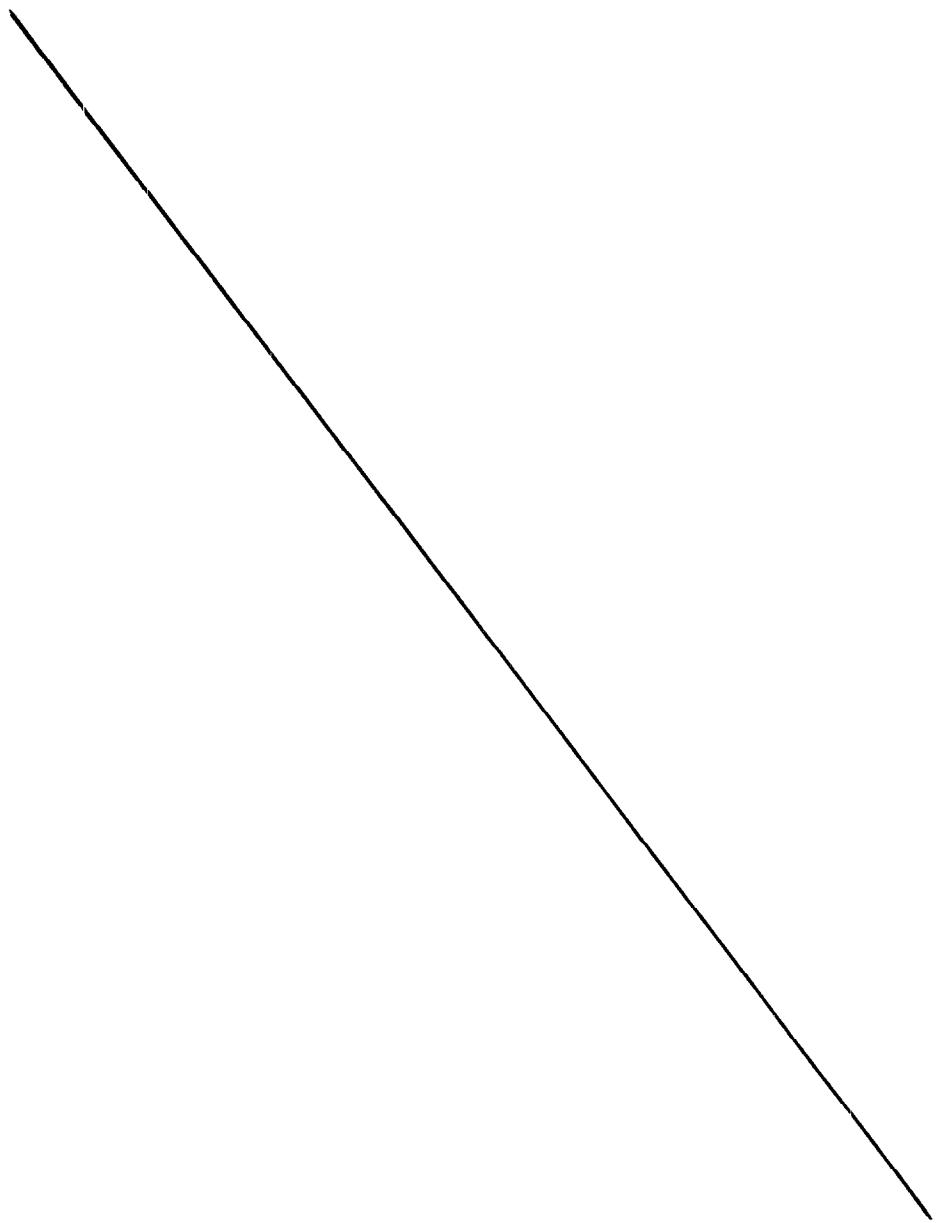
2.1 The Name of the Dietary Ingredient

The name of the new dietary ingredient manufactured by Natural Inc. is Omega-3 PL.



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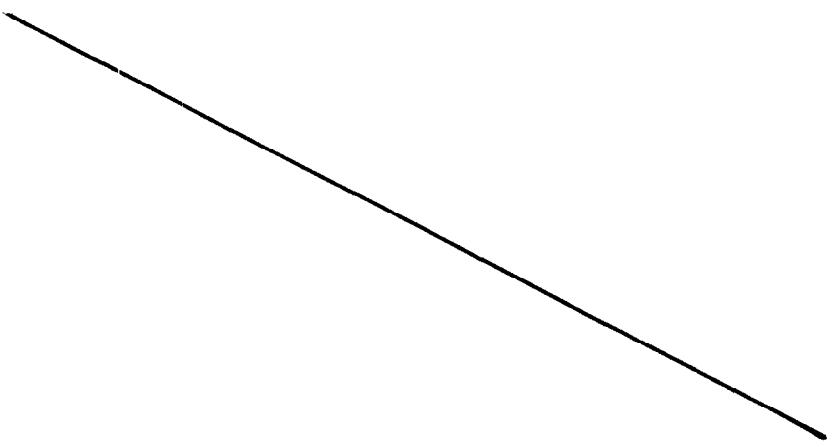
Figure 2.2.2-1 Manufacturing Process



SECTION 3

Description of the dietary supplement or dietary supplements that contain the dietary ingredient including (i) the level of dietary ingredient in the dietary supplement, and (ii) the conditions of use recommended or suggested in the labeling of the dietary supplement, or if no conditions of use are recommended or suggested in the labeling of the dietary supplement, the ordinary conditions of use of the supplement.

Omega-3 PL is a dietary supplement containing predominantly PL



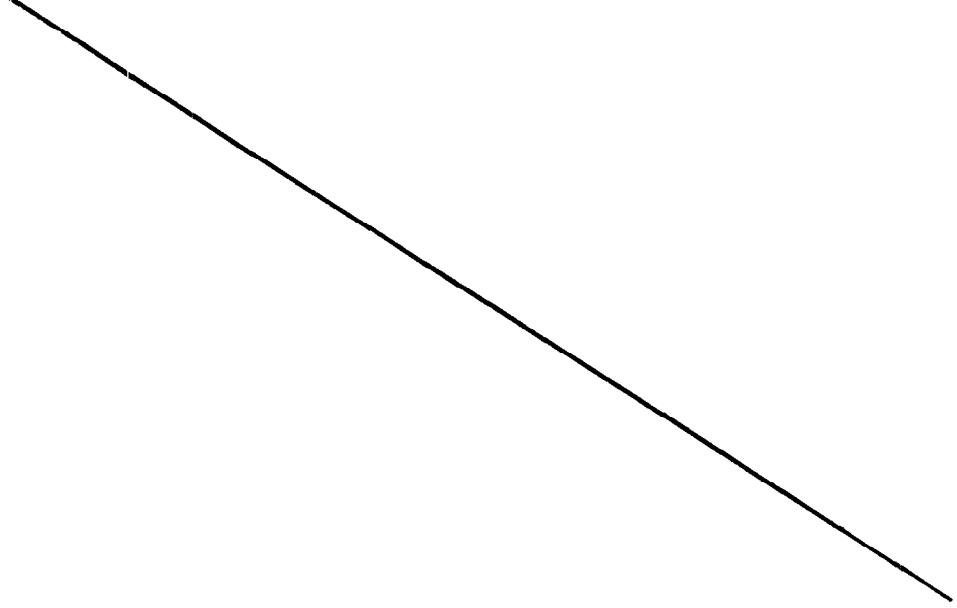
SECTION 4

The history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe, including any citation to published articles or other evidence that is the basis on which the distributor or manufacturer has concluded that the dietary supplement will reasonably be expected to be safe.

43 PAGES TOTAL

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4.7 Assessment of Safety



4.7.3 Omega-3 PL



Overall, the safety of the proposed New Dietary Ingredient, Omega-3 PL, is fully supported by extensive safety data

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